

Original Article

Feasibility and safety of rVSV-ZEBOV vaccination of humanitarian health workers against Ebola virus disease: an observational study

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Abstract

Background and rationale: Geneva University Hospitals were granted a temporary authorization to administer the recombinant live vesicular stomatitis virus rVSV-ZEBOV (Ervebo[®]) vaccine to expatriate humanitarian frontline workers (FLWs) prior to mission deployment.

Objectives: Our aims were to assess the feasibility of FLW vaccination before deployment and to report adverse events (AEs).

Methods: FLWs received a single injection of rVSV-ZEBOV (>7.2E7 plaque forming unit) during their pre-deployment medical check-up at the Travel Medicine Clinic of the Geneva University Hospitals (Day 0). A safety questionnaire regarding potential AEs was emailed to FLWs on Days 3 and 21. Early and delayed AEs were those starting within 3 or 21 days of vaccination, respectively.

Results: Between 1 August 2019 and 30 June 2020, 124 FLWs received the rVSV-ZEBOV vaccine. Eighty-six volunteers (86/124; 69%) received a concomitant vaccine. The response rate to the follow-up questionnaire was 88 and 55% at Days 3 and 21, respectively. Most respondents (105/109; 96.3%), experienced at least one AE, with a mean of three (\pm SD 1.75) AEs per person. The most common AE was injection site pain, followed by fever (53/109; 48.6%), fatigue (51/109; 46.7%) and myalgia (49/109; 44.9%). Most early AEs (360/377; 95.4%) resolved within 3 days, reflecting vaccine reactogenicity. Delayed AEs were reported by 6/69 (7.2%) subjects, the median time to symptom onset was 11 days (range: 5–14); half of them were joint-related AEs (3/6). Four serious adverse events (SAE) were observed: two cases of high grade fever, one rash and one case of arthritis. Two suspected unexpected serious adverse reactions were observed: one case of continuing recurrent transient dizziness and fatigue considered related to the vaccine; and one case of presbyopia that was deemed unrelated.

Conclusion: AEs to rVSV-ZEBOV were common but in general transient and were well tolerated, pre-deployment rVSV-ZEBOV vaccination in FLW is feasible and can be included with pre-mission check-up.

Key words: Ebola, vaccination, rVSV-ZEBOV, live vaccine, humanitarian health care, workers, rVSV-ZEBOV, Ervebo

Introduction

The 2014–16 West Africa Ebola virus (EBOV) disease (EVD) outbreak led to an acceleration in Ebola vaccine development. The recombinant live vesicular stomatitis virus (rVSV)-vectored vaccine expressing EBOV glycoprotein (rVSV-ZEBOV) induces dose-dependent immunogenicity and confers clinical protection against the Ebolavirus disease (EVD).^{1,2} Few SAEs have been described, but reactogenicity and viral dissemination to joints and skin, both self-limited, have been well documented.³

Vaccination of frontline workers (FLWs) has become a priority strategy against EVD. Yet rVSV-ZEBOV vaccine access is still restricted by its licenced status and/or its very limited availability, and administration may be delayed by administrative and logistical constraints such that many expatriate FLW can only be vaccinated upon arrival in the field. This delay, coupled with the time needed for antibody production (a minimum of 6–10 days post-vaccination),^{4,5} may increase the risk of contracting EVD.⁶ Moreover, early vaccine reactogenicity may mimic initial EVD symptoms,¹ causing major psychological stress to FLW and unnecessary medical work-up, if AEs happen in the field. In this context, the Geneva Center for Emerging Viral Diseases [Geneva University Hospitals (HUG)] was approached in January 2019 by Merck Sharp & Dohme (MSD), the vaccine manufacturer, who had been contacted by Médecins sans Frontières (MSF) and the International Committee of the Red Cross (ICRC) regarding potential vaccination of FLW prior to deployment to the Democratic Republic of Congo. At this time, rVSV-ZEBOV was not yet licensed as Ervebo®; its administration was restricted to clinical studies, emergency expanded access and/or compassionate use protocols. The HUG, which in 2014 sponsored the first investigator-initiated randomized Phase I/II trial,³ thus worked to establish a pre-deployment vaccination programme, which was granted temporary authorization in summer 2019 (TA 2019-00002). We describe the feasibility and safety of pre-deployment of rVSV-ZEBOV vaccination in a large cohort of FLW during the pre-mission medical appointment.

Methods

Two hundred 1-ml single-dose vials of rVSV-ZEBOV [$>7.2E7$ plaque forming unit (pfu)/ml] were shipped to HUG free of charge by the vaccine manufacturer. All adult expatriate FLW to be deployed to an EBOV zone were eligible for participation in the programme. Exclusion criteria were the same as those from the Swiss Phase I clinical trial (NCT02287480): immunosuppression, pregnancy, chronic hepatitis, renal or hepatic impairment, or having received a live vaccine in the preceding month or rVSV-ZEBOV at any time previously.^{1,3} Female volunteers were advised to not get pregnant within 2 months after vaccination. Humanitarian organizations' medical staff health personnel first screened their FLW for inclusion criteria, and each participant received the informed consent form days prior to the administration of the vaccine, which specified the nature of the vaccination programme.

Appointments were organized during the pre-mission briefing in Geneva to avoid delays in deployment. Vaccination was offered free of charge at the HUG Division of Tropical and Humanitarian Medicine (DTHM) during a pre-mission medical consultation. Counselling on infection prevention and

control measures to be observed in the field, regardless of the rVSV-ZEBOV vaccination status, was offered to all participants. All vaccinees received one dose of 1 ml ($>7.2E7$ pfu/ml) in the deltoid. When needed, other recommended vaccines were administered immediately (within minutes) after rVSV-ZEBOV injection.

Given extant safety data already available, active post-vaccination follow-up with AE documentation was limited to 21 days. Thereafter, vaccinees were asked to report AEs by contacting the vaccination team. SAEs were reported by the local pharmacovigilance team to Swiss authorities and by the programme manager to the vaccine manufacturer.

Nurses observed and solicited vaccinees for immediate AEs in the 30-min post-vaccination observation period. Follow-up of solicited and unsolicited early (≤ 3 days) and delayed (> 3 days) AEs was conducted by a questionnaire sent by email (Supplementary Figure S1 available as Supplementary data at *JTM* online) at Day 3 (± 2) and Day 21 (± 2) after vaccination. The questionnaire was sent twice in case of non-response. If the volunteer had an early AE requiring medical consultation, an appointment was set up at the DTHM. Fever was defined as temperature $\geq 38.0^\circ\text{C}$ whether tympanic, oral or axillary. All AEs considered possibly, probably or certainly related to the vaccine and all SAEs of any causality are reported here. Continuous data are presented as the mean [standard deviation (SD)] unless otherwise specified. Categorical data are presented as counts and/or percentages.

When needed for AE investigation, specific rVSV-ZEBOV real-time reverse-transcriptase polymerase-chain reaction (rRT-PCR) was performed on various clinical specimens, as previously described.³

Results

Between 1 August 2019 and 30 June 2020, 125 humanitarian Ebola FLWs were evaluated for vaccination; of these, 124 fulfilled the criteria (Figure 1). More than half were women (64/124, 51.6%); mean age was 41 years old (\pm SD 9.25, range: 25–70). Most (86/124, 69%) received other vaccines during the same visit, the most frequent being polio, typhoid-fever, rabies and flu vaccines (Table 1). All volunteers received a malaria-prophylaxis prescription; for 'Ebola missions', such prophylaxis is mandatory to minimize the risk of fever, and thus the additional stress, given the potential Ebolavirus exposure.

Immediate AEs

Immediate AEs are those which occurred within 30 min, and they were reported by all the participants for which data are available ($n = 117$); among these, 99/117 (84.6%) experienced pain at the injection site. In 46 (46%) and 12 (12%), the pain lasted < 24 h and ≥ 3 days (Table 2). Two spontaneously resolving vasovagal syncopes were observed immediately following vaccination.

Early AEs (Days 0–3)

One hundred and nine participants (109/124; 88%) answered the follow-up questionnaire sent 3 days after the vaccination. Most (105/109; 96.3%) had at least one AE deemed to be linked to the vaccine, with a mean of three AEs per person (\pm SD 1.75;

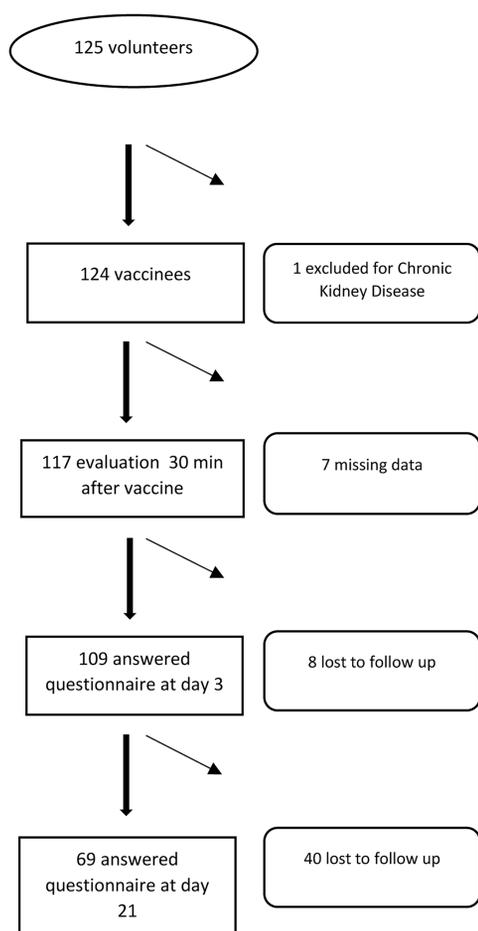


Figure 1. Flow chart of the data available of the cohort of patients.

range: 0–8). The most common AE remained pain at the injection site. Almost half reported fever (53/109, 48.6%), which resolved within the first 3 days in all cases. Fatigue, myalgia and headache were also frequently described (Table 2).

A vesicular rash was observed in two participants. In one vaccinee, a vesiculo-papular rash on the shoulder, deemed to likely be vaccine-related, began 2 days after vaccination (Figure 2A). It progressively extended to the back and along the extremities (Figure 2B), and it resolved at Day 10. Tests for rVSV-ZEBOV by a specific RT-PCR in plasma samples and in a swab of expressed vesicular fluid were negative. The rash in the second vaccinee may have already appeared before vaccination and was therefore considered only possibly linked to the vaccine. Table 2 presents the mean duration of symptoms. Two suspected unexpected serious adverse reactions (SUSARs) were observed, one of which was considered possibly linked to the vaccine, are described below. Most AEs (360/377, 95.4%) resolved within 72 h. Roughly a quarter (31/109, 28.4%) of symptomatic vaccinees took medication (analgesics and/or antipyretics) for the AE.

Delayed AEs (Days 4–21)

Among the 69 respondents at Day 21 (69/124, 55.6%), 6 (6/69, 7.2%) reported having had at least one and a maximum of three AEs appearing >3 days after vaccination (Table 2):

Table 1. Baseline characteristics of 124 humanitarian workers vaccinated against EVD at the Geneva University Hospitals

	Vaccinated FLW (n = 124)
Age (year)	41 (25–70)
Female	64 (52%)
Male	60 (48%)
Humanitarian organization	
MSF	107 (86.3%)
ICRC	12 (9.7%)
Other NGO	5 (4%)
Number of vaccines co-administered with rVSV-EBOV ^a	
None	38 (31%)
One	21 (17%)
Two	18 (15%)
Three	20 (16%)
Four	10 (8%)
Five	13 (10%)
Six	4 (3%)

^aThese include diphtheria, tetanus, pertussis, typhoid fever, measles, mumps, rubella, hepatitis A, hepatitis B, conjugate meningitis ACWY, influenza, poliomyelitis, rabies and yellow fever vaccines.

MSF, *médecins sans frontières*; ICRC, international committee of the red cross.

one SUSAR (see below and supplementary material); one case of transient pain at injection site 2 weeks after vaccination; two cases of arthralgia comprising one case of bilateral metacarpophalangeal joint pain lasting 48 h treated with paracetamol, and one case of unilateral wrist arthralgia lasting less than 24 h with a spontaneous resolution; and one case of arthritis of the metacarpophalangeal joint of the index finger lasting 3 days and resolving spontaneously. As the vaccinee was already in the field, by the time he experienced the AE, the diagnosis of arthritis was based on the description of the symptoms. Due to distance and transient nature for all of these delayed AEs, except the SUSAR, further investigation could not be performed.

SAE and SUSAR

In total, four AEs (4/109, 3.7%) were considered as SAEs by the HUG pharmacovigilance team and were likely or possibly linked to the vaccine: two cases of high grade fever (>39°C), one vesiculo-papular rash and the transient case of arthritis, which all spontaneously resolved.

Two vaccinees experienced a SUSAR (2/109, 1.8%): one was a persistent neurological AE that presented with continuing recurrent transient dizziness and fatigue, which led to repatriation from the field but no hospitalization. The aetiology remained unknown despite extensive investigations, including testing for live vesicular stomatitis virus-vectored vaccine expressing EBOV glycoprotein (Ervebo[®]) (rVSVΔG-EBOV-GP) by rRT-PCR in the cerebro-spinal fluid and plasma. The symptomatology improved progressively, but sequelae with transient iterative dizziness and fatigue persisted at 9 months (time of the latest available follow-up). Further description of the episode is available in the supplementary material. The event was considered possibly linked to the vaccine, because of its timing, in a volunteer who received concomitant typhoid (Typhim Vi[®])

Table 2. Early and delayed AEs following vaccination

Symptom	Early AE N (%), total: 109 patients	Duration ^c days, mean (+/-SD)	Delayed AE N (%), total: 69 patients	Duration ^c days, mean (+/-SD)
Abdominal pain	7 (6.4)	1 (0.76)	0	
Arthralgia	29 (26.6)	1.65 (1.86)	2 (0.3)	1.5 (0.5)
Arthritis	0	0	1 (1.4)	4 (NA)
Fatigue	51 (46.7)	1.39 (0.93)	0	
Chills	33 (30)	1.5 (0.86)	0	
Diarrhoea	3 (2.7)	1.3 (1.25)	0	
Fever	53 (48.6)	1.18 (0.87)	0	
Headache	32 (29.3)	1.4 (1.77)	0	
Myalgia	49 (44.9)	1.5 (0.5)	0	
Nausea	6 (5.5)	2.83 (3.3)	0	
Pain at injection site	99 ^a (84.6)	1.3 (3.68)	1 (1.4)	<1 (NA)
Rash	2 (1.8)	10 ^b (NA)	1 (1.4)	1 (NA)
Other	13 (11.9)	1.3	1 (1.4)	(NA)
Patient with ≥ 1 AE	105 (96.3)		6 (7.2)	

NA: non-applicable. Early AEs started within the first 3 days. Delayed AEs started and were declared after the first 3 days. Other: dizziness ($n = 4$), hunger ($n = 1$), nasal congestion ($n = 1$), loose stools ($n = 3$), difficult to concentrate (1), malaise (2), back pain (1) and vestibular syndrome (1). The symptoms of the patient with the complex neurological complain classified as SUSAR are listed both in the early and in the delayed AEs because part of her symptoms started the day after the administration of the vaccine (fever, asthenia, myalgia and arthralgias), while at Day 5, the neurological symptoms appeared.

^aIncludes immediate AE; $n = 117$.

^bData available only for one participant.

^cSUSARs were excluded for the calculation of the mean duration of the symptoms because they are still ongoing at the time of the writing of the manuscript.



Figure 2. Vesiculo-papular rash observed on a volunteer at Day 2 on the shoulder (A) and the thumb (B).

and rabies (Rabipur[®]) booster injections. The other SUSAR was experienced by a 45-year-old man who complained of a long-term visual blurring, which was later diagnosed as presbyopia and thus deemed unrelated to the vaccine.

Discussion

Our experience shows that pre-departure vaccination against EVD provides the optimal conditions for vaccination against EVD and is well accepted by expatriate humanitarian FLWs. The programme ensured access to Ebola vaccinations while waiting for a vaccine to be marketed. This vaccination can be integrated into the general pre-mission medical check-up offered before departure and can be performed by trained staff in travel medicine and expatriate health, who can answer any further questions about malaria prophylaxis, stress on missions,

post-exposure prophylaxis in cases of EVD or HIV exposure and general travel advice. In this regard, when needed, as part of the reality of the pre-mission medical check-up, regular vaccination schedules could be completed at the same time as the rVSV-ZEBOV was administered, as the benefit/risk balance argued for protection of FLWs. Of note, vaccination against EBOV does not dispense with the need to follow the strict and special infection prevention control measures inherent to any Ebola mission.

Consistent with what has previously been published for primary rVSV-ZEBOV vaccination, after which up to 98% of the subjects presented with early AE,^{1,3,7} most vaccinees had moderate symptoms related to the reactogenicity of the vaccine that resolved within 72 h. Of note, because several vaccines were administered at the same time in most of our volunteers, each vaccine may have contributed to the AEs, and causality is difficult to establish with a high degree of certainty for any single vaccine. It is possible that AEs and SAEs of rVSV-ZEBOV were exacerbated because of concomitant administration of other pre-travel vaccines. This is the first report of co-administration of other vaccines with rVSV-ZEBOV; due to multiple different combinations of co-administered vaccines and the low number of vaccinees of our cohort, data are insufficient to draw a conclusion on this topic and further investigation is needed.

Vaccinating before departure allowed FLWs to arrive in the field after the resolution of vaccine-related symptoms, thus avoiding the concern of vaccine accessibility upon arrival in the field, sick-leave days during the mission and the stress of having fever during an EBOV mission.

Enquiry of AEs by email without a subsequent clinical evaluation may lead to underreporting of AEs. By the time the second questionnaire was sent at 21 days after vaccination, all the participants had left to the field, and only half of the vaccinees (55%) responded.

Despite this low response rate, we believe that these reported AEs accurately represent the impact of vaccination related AEs on the mission and whether it was possible to manage them at a distance. In case of symptom persistence, vaccinees could contact the vaccination team for advice; we believe that it adequately represents the reality in the field, where it is important to have a reference medical team to consult in the case of symptoms. With the development of remote medical consultations, appointments or follow-ups could also be organized by telemedicine in the field.

One prolonged SUSAR led to the repatriation of the FLW. The neurological manifestation and persistent fatigue were subject to extensive investigation and have not previously been reported after rVSV-ZEBOV vaccination despite the large-scale distribution of the vaccine in the field during EVD outbreaks. However, those symptoms may have been unnoticed in remote areas with limited access to medical care. While rVSV-ZEBOV is now marketed as Ervebo[®], continued reporting of potential AEs to competent authorities should continue. Of note, concomitant administration of other vaccines may have played a role in the development of the SUSAR. Sixteen vaccinees in our cohort were administered with a combination of anti-typhoid, anti-rabies and anti-Ebola vaccines and sometimes with other more vaccines; all of their AEs resolved within 3 days and were compatible with known reactivity (data not shown).

As per the authorization protocol, exclusion criteria included a previous immunization with the rVSV-ZEBOV at any time, or with a live vaccine 1 month prior, and an existing immunosuppression. While humanitarian FLWs may be sent on several EVD outbreaks over the years, the need, the timing and the choice of a booster should further be investigated.⁸ With the arrival of other anti-Ebola replication defective vaccines on the market,⁹ Zabdeno[®] (Ad26.ZEBOV) and Mvabea[®] (MVA-BN-Filo), one will have to determine the best option, balancing safety and immunogenicity, and head-to-head comparisons of those vaccines will help to determine which one best meets the needs of the FLWs.

Conclusion

Our experience with FLWs' vaccination against EVD has proven vaccination to be feasible before departure and safe if a subsequent follow-up can be ensured by remote medical follow-up. It should be integrated into the general pre-mission check-up. By administering the vaccine before departure, most of the AEs are resolved before arrival in the field, allowing for more effective and less stressful work.

However, the description of delayed AEs requires a benefit-risk assessment to be conducted before vaccination and reserving the vaccine for people clearly at risk of EVD exposure, such as humanitarian FLWs or other travellers such as visiting friends and relatives (VFR), who cannot postpone travel to a region with an ongoing declared outbreak.

While new EVD outbreaks are regularly declared, both the previously vaccinated local population and FLWs may be re-exposed to the disease. Therefore, the length of the elicited immune response after vaccination has become a key question as well as the subsequent need for a booster.^{8,10} An ideal vaccine should be safe and offer a cross-protection against other Ebola species, without eliciting antibody dependent enhancement, both

in immuno-competent and in immuno-suppressed persons. In the field, the wider use of vaccines and new therapies has already altered EVD's spectrum, transforming it from a deadly illness to a preventable and treatable disease.^{11,12}

Supplementary data

Supplementary data are available at *JTM* online.

Authors' contributions

P.V. and L.K. are in charge for the authorization from the Swiss Agency of Therapeutic Products. P.V., A.H., L.K., G.E. and F.C. wrote the protocol. P.V. was in charge of the collection of the AE and the reporting to the Swiss Agency of Therapeutic Products. L.C., G.E., F.C. and S.A.-P. were in charge of the administration of the vaccine. L.C. and P.V. did the statistical analysis and the data interpretation and wrote the first draft of the manuscript. All authors critically reviewed the manuscript.

Transparency declaration

P.V. and N.P. have been involved in Ebola vaccination in the Democratic Republic of the Congo with 'MSF'.

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Conflict of interest: None declared.

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